> PATENT 70063-00004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho

Serial No.: 10/599,779 Art Unit: 1617

Filed: 06/28/2007

Examiner: Gina Yu

Title: SKIN LIGHTENING METHOD

## APPEAL BRIEF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir or Madam:

The appellant filed a Notice of Appeal in the above-identified application on August 27, 2010 under 35 U.S.C. § 134(a). The appellant requests entry, consideration, and favorable action on this appeal at the Office's earliest convenience.

In accordance with Rule 41.37(c), the appellant presents the following items under the headings prescribed therein.

Serial No. 10/599,779 November 1, 2010 Page 2

# TABLE OF CONTENTS

Real Party in Interest	3
Related Appeals and Interferences	3
Status of Claims	3
Status of Amendments	3
Summary of Claimed Subject Matter	3
Grounds of Rejection to Be Reviewed on Appeal	4
Argument	4
Conclusion	. 11
Appealed Claims Appendix	. 12
Evidence Appendix	. 13
Related Appeals and Interferences Appendix	. 37

Page 3

Real Party in Interest

Thienna Ho, an individual residing in California, owns the subject application.

Related Appeals and Interferences

None

Status of Claims

The Official Action mailed on May 28, 2010 (hereinafter the "Final Action"), finally

rejected claims 1, 4-6, 9-11, 13, 15, 17 and 19. Claims 2-3, 7-8, 12, 14, 15 and 18 were

cancelled prior to the Final Action. No other claims are pending.

Status of Amendments

All amendments to the pending claims were submitted and entered prior to the

Final Action.

Summary of Claimed Subject Matter

This section includes a concise explanation of the subject matter defined in the

independent claim involved in the appeal (i.e., claim 1), which includes references to the

specification and drawings as specified in Rule 41.37. What is disclosed in the

specification are embodiments of the corresponding claim elements.

Claim 1 defines a method for causing a person to develop a skin tone noticeably

lighter than the person's natural skin tone comprising:

(A) "delivering an effective amount of methyl sulfonyl methane to a person for

developing a lighter skin tone by ingestion of the effective amount, at least until the

person develops a skin tone noticeably lighter than before commencement of the

Page 4

delivery step, wherein the effective amount comprises orally administered doses in an

amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per

day continuing for not less than three months." Please see, for example, p. 1, line 28 to

p. 2, line 15; p. 6, lines 13-22; Table I, p. 7.

Grounds of Rejection To Be Reviewed on Appeal

Review of the following grounds of rejection is sought on appeal:

The rejection of claims 1, 4-6, 9-11, 13, 15, 17 and 19 under 35 U.S.C. § 103(a)

as being unpatentable over Herschler (Pat. No. 4,296,130) in view of Webster's Ninth

New Collegiate Dictionary (1991) (hereinafter, "Websters") and Salim (WO 1994/05279,

Claims 4-6, 9-11, 13, 15, 17 and 19 stand or fall with base claim 1.

Argument

in the arguments below, the appellant presents reasons why defined groups of

claims are separately patentable over the cited references.

Rejections of Claims 1, 4-6, 9-11, 13, 15, 17 and 19 Under 35 U.S.C. § 103

Claim 1 defines "delivering an effective amount of methyl sulfonyl methane to a

person for developing a lighter skin tone by ingestion of the effective amount, at least

until the person develops a skin tone noticeably lighter than before commencement of

the delivery step." Claim 1 further defines that "the effective amount comprises orally

administered doses in an amount of at least 133 mg of methyl sulfonyl methane per

kilogram of body weight per day continuing for not less than three months." The

Page 5

combination of Herschler, Websters and Salim fails to disclose or make obvious both of

these elements defined by claim 1.

It is undisputed that Herschler discloses that compositions including methyl

sulfonyl methane (MSM) can be "used effectively to soften skin, to dilute blood, and for

a variety of other useful purposes." Col. 2:18-21. It is also undisputed that Herschler

discloses oral administration of MSM to rats in an amount of 20 grams per kilogram per

day for six weeks, to demonstrate non-toxicity only and not to show any efficacious

result. Example 16 at col. 11. It is acknowledged that Herschler does not disclose oral

administration of MSM in the dosage defined by the present claim. Final Action, p. 3.

The Final Action relies heavily on Herschler's disclosure that:

MSM has proved to have varied and useful properties when applied to any animal tissue subject to undesired chemical bond formation including cross-linking. It has been observed to beautify the complexion, to enhance scalp and hair, and generally to help make the body of the user

more flexible and comfortable.

Col. 2:29-35. Based on this passage and on a dictionary definition of "complexion" the

Final Action found that:

It would have been obvious to one of ordinary skill in the art at the time of the present invention that the Herschler method of administering MSM to human subjects would bring about changes to, and/or improve, the color and skin tone and/or overall appearance of the skin because the reference teaches MSM "beautifies the complexion" of the skin, and the Webster dictionary indicates that complexion refers to the color or appearance of skin in the cosmetic art. Thus applicant's claim of development of "a skin tone noticeably lighter than the person's natural skin tone" by administering MSM to the patient would naturally flow from practicing the Herschler method, which would have been observed by one of ordinary skill in the art.

43845\_1

Page 6

Final Action, p. 3-4. These findings constitute reversible error, for the reasons discussed below.

First, although "complexion" has different meanings that can include skin tone, in

the context of Herschler it does not refer to skin tone. Instead, the phrase "beautify the

complexion," as used by Herschler clearly refers to the cosmetic effect of providing the

skin a softer, smoother texture and more youthful appearance. See, e.g., col. 2:29-34

(MSM "useful when applied to any animal tissue subject to undesired chemical bond

formation"); col. 3:15-17 ("effective in softening, smoothing or comforting the skin"); col.

3:31-34 ("soften, smooth and lubricate the skin"); col. 3:36-37 ("resist cross-linking of

collagen"); col. 7:15-19 ("the softness and pliancy associated with youthful, healthy skin

thus can be maintained"); col. 7:62-64 (a substantial softening and smoothing of the

skin was observed"); and col. 10:1-2 ("noted a substantial improvement in skin softness,

smoothness and comfort." Herschler contains absolutely no discussion of skin color or

tone. Therefore one or ordinary skill, upon reading Herschler, would have concluded

that MSM is useful for beautifying the skin by rendering it more pliable and smoother, or

by reducing irritation, but would not have received the slightest suggestion that MSM

might alter natural skin color in any way.

Herschler's failure to disclose or suggest any lightening of skin tone by use of the

phrase "beautify the complexion" or otherwise is confirmed by two declarations already

of record in this application; The Declaration of Dr. Nikolay N. Barashkoy ("Barashkoy")

and The Declaration of Sherilee J. Backman ("Backman"). Ms. Backman, being a

Serial No. 10/599,779

November 1, 2010

Page 7

cosmetic chemist, represents someone with the background and experience of one "of

ordinary skill in the art." Dr. Barashkov's background in physical and organic chemistry

may also be relevant, and is worthy of consideration as from one of skill in the art. Ms.

Backman confirms the appellant in that the finding in the Final Action "does not

accurately reflect what would have been obvious to a cosmetic chemist when the

present patent application was first filed as an international application in April 2005."

Backman § 5. Dr. Barashkov confirms that "[t]he phrase "beautify the complexion."

which is mentioned by Herschler as one of applications for methylsulfonylmethane

(MSM), undoubtedly refers to providing the skin a softer, smoother texture and

appearance," and would not have suggested lightening skin tone. Barashkov ¶ 4-5.

Moreover, both organic and cosmetic chemists would have understood the phrase

"beautify the complexion" as used by Herschler to refer only to the softening and

smoothing effect of MSM that Herschler described, and not to any skin lightening effect.

Barashkov § 6-8; Backman § 7.

In addition, the entire disclosure of Herschler shows absolutely no recognition or

conception that MSM has any effect on skin tone. "The Herschler patent does not

anywhere disclose or imply that MSM lightens skin tone or coloration. . . Among other

things, at the time the Herschler patent was written (1979) and even much later it was

not known that MSM exhibited a tone-lightening effect on skin." Barashkov ¶ 5. In

addition, Ms. Backman declares that:

It is self-evident from his disclosure that Herschler had not conceived of

Page 8

using MSM for skin lightening or brightening and therefore could not have used the phrase beautify the complexion" to refer to any such effect. For example, Herschler does not mention vitiligo, hyperpigmentation, or any other disease affecting skin color, at all. His patent is focused on the stabilization of urea (carbamide) by combining it with MSM, and using this combination to "beautify the complexion" by softening and smoothing the skin. In column 3 of his patent, he writes "An object is to provide a stable, neutral vehicle for pharmaceuticals, which vehicle has no interfering or undesirable pharmacological activity." Furthermore, if Herschler were interested at all in skin lightening, he would have mentioned hydroquinone, or some other known skin lightening agent, in his table of "actives" in column 13. The fact that he mentions no such agent evidences his lack of knowledge or interest in skin lightening as an effect of his cosmetic compositions

Backman ¶ 6. The testimony of Dr. Barashkov and Ms. Backman, in light of the disclosure of Herschler and Webster's definition of "complexion," persuasively shows that Herschler fails to disclose or suggest "delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step." The testimony of these chemists demonstrates that Webster's dictionary definition of "complexion" in combination with Herschler would not have suggested the use of MSM to lighten or change skin tone. The reasoning stated in the Final Action to the contrary is evidently based on an erroneous finding, and the rejection of claim 1 should therefore be reversed.

The Final Action does not argue that any dose regimen taught by Herschler would inherently result in lightening of skin tone, and appellant is not aware of any basis supporting such a finding. On the contrary, as acknowledged in the Final Action, Herschler also fails to disclose "wherein the effective amount comprises orally

Page 9

administered doses in an amount of at least 133 mg of methyl sulfonyl methane per

kilogram of body weight per day continuing for not less than three months," as also

defined by claim 1. Final Action, p.3. The Final Action erroneously cites Salim as

disclosing this element, and the error in the finding is demonstrated below. It is

undisputed that Salim fails to disclose or suggest that MSM or anything else can be

used to lighten skin tone, and is not generally concerned with skin tone.

Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of

from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as

healing injured skin, in combination with a sulfur-containing amino acid. Salim, p. 7 first

paragraph; Backman ¶ 9. A cosmetic chemist of ordinary skill would understand Salim

as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg

three or four times daily, or smaller doses more frequently), in combination with one or

more sulfur-containing amino acids in the same dosage range. Backman § 9. For a 45

kg adult female, Salim therefore discloses a maximum dose of MSM in the range of 33

to 44 mg/kg/day. Backman ¶ 9. Therefore, a reasonable reading of Salim leads to the

conclusion that Salim taught maximum oral doses of MSM significantly less than

claimed.

Moreover, there would have been no motivation for someone reading Herschler

and Salim to discover the dose regimen defined by claim 1, because lower doses were

already known to be effective for all known cosmetic and therapeutic applications, as

demonstrated by the Herschler and Salim references. Backman ¶ 10. There was no

43845\_1

Page 10

suggestion that higher doses of MSM would produce any beneficial effect, so there

would have been no reason to experiment with higher doses. Id. For example, Salim

teaches that increasing the concentration of MSM does not provide any additional

benefit in reducing tissue injury, as reported in its tables on pages 11 and 13.

Therefore, Salim provides no incentive to experiment with higher doses, and if anything,

might have discouraged such experimentation by reporting that increased

concentrations of MSM provide no additional benefit. Backman ¶ 11; Salim p. 11-13.

In addition, MSM's skin lightening effects would not have been considered

expected or predictable at the time these effects were first reported by appellant in the

present application. Backman ¶ 8. Skin lightening is an unexpected result of

administering MSM. Barashkov 1/9.

In summary of the foregoing, the evidence shows that the combination of

Herschler, Webster's and Salim fails to disclose each and every element of claim 1.

The references and enclosed declarations also show that those of skill in the art would

have had no motivation to administer the claimed oral doses. In addition, the

declarations show that the skin lightening effect provided by the claimed dose regimen

would have been unexpected. Claim 1 therefore recites a combination of elements that

was not known, would not have been obvious at the time the invention was made, and

which leads to an unexpected result. The Final Action does properly support any

findings contrary to the foregoing.

in view of the deficiencies of Herschler, Webster's and Salim outlined above.

Page 11

these references pose no bar to patentability of claim 1, which is therefore allowable.

The remaining claims 4-6, 9-11, 13, 15, 17 and 19 are also allowable, at least as

depending from an allowable base claim.

Conclusion

In view of the foregoing, Appellant respectfully requests the reversal of the

rejection of currently pending claims 1, 4-6, 9-11, 13, 15, 17 and 19, and allowance of

these claims forthwith.

Appendices

Appealed claims 1, 4-6, 9-11, 13, 15, 17 and 19 are attached hereto as Appendix

A. Evidence for consideration in this appeal is attached hereto as Appendix B. Related

Appeals and Interferences, if any, are listed in Appendix C.

Respectfully submitted,

Date: November 1, 2010

/Jonathan Jaech/

Jonathan Jaech for Appellant

Reg. No. 41,091

CUSTOMER

Connolly Bove Lodge & Hutz LLP

333 South Grand Avenue

Suite 2300

Los Angeles, CA 90071-1560

(213) 787-2500

58688

Page 12

APPENDIX A

APPEALED CLAIMS

1. (Previously presented) A method for causing a person to develop a skin

tone noticeably lighter than the person's natural skin tone, comprising delivering an

effective amount of methyl sulfonyl methane to a person for developing a lighter skin

tone by indestion of the effective amount, at least until the person develops a skin tone

noticeably lighter than before commencement of the delivery step, wherein the effective

amount comprises orally administered doses in an amount of at least 133 mg of methyl

sulfonyl methane per kilogram of body weight per day continuing for not less than three

months.

2-3. (Canceled)

4. (Previously presented) The method of claim 1, further comprising

delivering the effective amount of methyl sulfonyl methane by periodically ingesting in a

compound comprising methyl sulfonyl methane and other ingredients.

5. (Original) The method of claim 4, further comprising delivering the

effective amount of methyl sulfonyl methane by ingesting the compound further

comprising at least one nutrient selected from vitamins, minerals, antioxidants, proteins,

and amino acids.

49845\_1

Page 13

6. (Previously presented) The method of claim 1, further comprising

delivering the effective amount of methyl sulfonyl methane also by periodic topical

application of a compound comprising methyl sulfonyl methane.

(Canceled).

8. (Canceled)

9. (Previously presented) The method of claim 1, further comprising

delivering a portion of the effective amount of methyl sulfonyl methane in a compound

comprising about 1 to 20 weight percent methyl sulfonyl methane for topical application.

10. (Previously presented) The method of claim 1, further comprising

delivering a portion of the effective amount of methyl sulfonyl methane in a compound

comprising greater than about 20 weight percent methyl sulfonyl methane for topical

application.

11. (Previously presented) The method of claim 1, further comprising

delivering a portion of the effective amount of methyl sulfonyl methane in a compound

comprising about between about 20 to 22 weight percent methyl sulfonyl methane for

topical application.

12. (Canceled)

Page 14

13. (Original) The method of claim 1, further comprising delivering an exfoliate

to the person during the delivery of the methyl sulfonyl methane.

14. (Canceled)

15. (Original) The method of claim 6, further comprising delivering an exfoliate

to the person during the delivery of the methyl sulfonyl methane.

16. (Canceled)

17. (Original) The method of claim 1, wherein the delivering the effective

amount of methyl sulfonyl methane is performed at least about daily.

18. (Canceled)

19. (Original) The method of claim 6, wherein the delivering the effective

amount of methyl sulfonyl methane is performed at least about daily.

20. (Canceled)

43845\_1

Serial No. 10/599,779 November 1, 2010 Page 15

## APPENDIX B

# **EVIDENCE**

The Declaration of Dr. Nikolay N. Barashkov ("Barashkov") and

The Declaration of Sherilee J. Backman ("Backman")

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thlenna Ho

Serial No.: 10/599,779

Filed: 06/28/2007

Title: SKIN LIGHTENING METHOD

Art Unit: 1617

Examiner: Gina Yu

## Declaration Under 37 CFR Section 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Dear Sir or Madam:

- I, the undersigned Dr. Nikolav N. Barashkov, declare and sav:
- 1. I have more than thirty years of experience in area of spectral research in chemistry and medico-biological applications, both in academia and industry, including specialty chemicals, biotechnology, as well as food and animal feed industry, and have applied for and obtained numerous patents in my field. I hold doctoral degrees in Organic Chemistry and Polymer Chemistry and Preysical Chemistry from the Karpov Institute of Physical Chemistry in Moscow, Russia. Further details concerning my academic training, work experience, publications and activities are presented in my résumé attached as Exhibit A to the present declaration.
  - 2. I have received no compensation in exchange for submitting this

Senal No. 10/599,779 December 7, 2009 Page 2

declaration, and have no personal interest or stake in the outcome of the abovereferenced patent application.

- I have reviewed and am familiar with the above-referenced patent application. Serial No. 10/599,779, Skin Lightening Method. I have also reviewed U.S. Patent No. 4.296,130 ("Herschler") and the most recent office action of the present application, dated November 13, 2009.
- 4. The phrase 'beautify the complexion," which is mentioned by Herchier as one of applications for methylsulfonylmethane (MSM), undoubledly refers to providing the skin a softer, smoother texture and appearance. Softening was evidently important to Herschler because it is expressly named in the second of only two total daims of the Herschler patent. The Herschler patent also discusses the softening and smoothing skin effect of MSM in numerous places, and claims that MSM provides anti-aging benefits for skin by making skin more pilable (i.e., softer).
- 5. The Herschler patent does not anywhere disclose or imply that MSM lightens skin tone or coloration. Instead, with respect to skin the Herschler patent repeatedly discloses only that MSM makes skin softer, smoother and more pilable. If Herschler had intended "beautify the complexion" to also refer to lightening skin tone, he would have expressly described a tone lightening effect. Among other things, at the time the Herschler patent was written (1979) and even much later it was riot known that MSM exhibited a tone-lightening effect on skin. Therefore this effect could not have been presumed from the general phrase "beautify the complexion," absent any explicit disclosure of a skin tone lightening effect by Herschler.
- The word "complexion" has no special technical meaning in organic or physical chemistry relevant to the appearance of skin.

Serial No. 10/599,779 December 7, 2009 Page 3

- 7. The word "complexion" may itself have several possible meanings from ordinary use. From my experience in the ordinary use of English, people sometimes refer to a "light complexion" or a "dark complexion" when referring to skin tone. However a phrase like "beautiful complexion" would not be considered as referring to skin tone, because beauty is not considered limited to skin of a particular color by most people. In fact many in America would have considered (and still would consider) it offensive or racist to imply that skin of a lighter color is "more beautiful" than skin of a darker color. Therefore, a chemist of ordinary skill writing a patent application in 1979 would not have used "beautify the complexion" to refer to lightening skin tone, first of all because the phrase would not have been understood in the intended way, and second of all because use of the phrase to mean lightening skin tone would have risked offending the reader.
- 8. For the reasons explained in the foregoing paragraphs, an organic chemist of ordinary skill, upon encountering the phrase "beautify the complexion" in the Herschler patent would have understood the phrase to refer only to the softening and smoothing effect of MSM that Herschler described, and not anything else.
- 9. From my experience and training in organic and physical chemistry, I am not aware of MSM or any similar substance being known or recognized as capable of lightening skin tone when administered to a human or animal. Skin lightening is an unexpected, not predictable result of administering MSM that was first reported, so far as I know, by the inventor of the present patent application Serial No. 10/599,779.
- 10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false

Serial No. 10/599,779 December 7, 2009

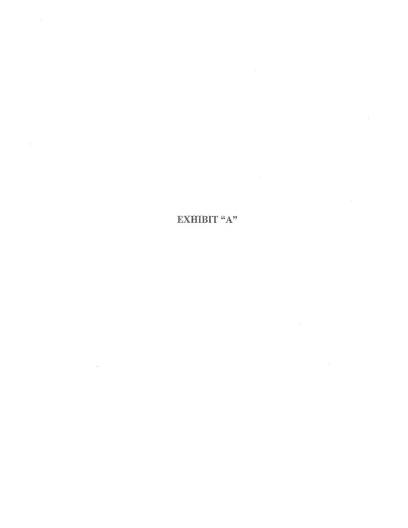
Page 4

statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: December 7,2009

Dr. Nikolay N. Baráshkov



SUMMARY

30+ years of experience in area of spectral research (mainly fluorescent research) in chemistry and medicolological applications, both in academia and industry, including specialty chemicals, biolechnology, as well as food and aminal feed industry. Proven ability to apply knowledge of organic chemistry and physical chemistry, simultaneously work on multiple batches of high complexity and recommend process improvements in such areas, as preparation of dozens new fluorescent dyse-monomers, and hundred new polymers, identification and characterization of prepared compounds by HPLC, NMR, FTIR, MS, GPC, UV-Via, fluorescent spectroscopy and other physico-chemical methods. Team player who works well with others and has good skills in writing proposals. Has desire to learn and ability to adapt well to new projects and environments.

#### PROFESSIONAL EMPLOYMENT AND EXPERIENCE

Micro Tracers, Inc., San Francisco, CA

Director of R&D and Technical Services

01/2008-Present

Applied research and development in the areas of chlorine-free methods for sterilization of contaminated waters, as well as creation of new microtracers, including nanosized microtracers.

\*Created new chlorine-free electrolytic and photochemical methods for sterilization of contaminated waters (presentation at two ACS Meetings, 2006 and 2007, submitted SBIR Proposal for EPA);

'Developed new alumina-based and silica gel-based microtracers for feed and pharmaceutical industries:

"Created ferromagnetic nanoparticles suitable for making liquid microtracers;

\*Provided analytical support in characterization of existing fron-based microtracers, as well as selentum-based products manufactured by Micro Tracers, inc.

ANRESCO Laboratories, San Francisco, CA Senior Consulting Chemist HPLC analysis of aflatoxins and vitamins

10/2005-12/2005

Biotlum,Inc, Hayward, CA Senior Scientist

2004-2005

Applied research in the area of the synthesis of small molecules, such as fluorescent dives and related blochemical reagents for life science and drug discovery, as well as in the area of protein chemistry.

\*Developed new Ethidium Homodimer III which is capable to form the fluorescent complexes with double-strained DNA and has higher binding affinity compared to known homodimers

"Proposed improved synthetic procedures for making fluorescent calcium indicators; membrane potential dyes; fluorogenic attention procephatase substrates; bioluminescent enzyme substrates; fluorogenic peptidiate substrates; biotin derivatives used as the cellular tracery.

\* Developed QC procedures, including HPLC and NMR evaluation of final products.

Radiant Color, Richmond, CA Senior Research Scientist

1997-2004

Applied research, scale-up and development in the areas of small molecules, such as fluorescent dyes, fluorescent polymers and polymer-dye compositions:

\*Planed and prioritized numerous projects; managed all aspects of the development process being a leader of the technical group consisting of one Senior Chemist and two technicians.

"Handled scale-up processes in-house to supply new fluorescent pigments on 50-80 lbs scale.

"Proposed and developed new methods of fluorescent dyes' modification by incorporation of functional groups (together with Keystone Antiline Corporation and Advanced Synthesis, Inc).

"Proposed and carried out new synthetic routes for making fluorescent pigments with improved color development and high level of lightfastness (2 US patents and 3 Eurosean patents granted).

\*Created method for preparation of spherical nanoparticles (size below 150 nanometers) of polymer-dye compositions for ink jet technology and military application (US patent pending, submitted Proposal for STIR Program of Dob).

\*Investigated photophysical behavior of organic compounds which show unique aggregationinduced emission from nanopartities (size 40-120 mm) (Together with institute of Nano Science and Technology, Hong Kong, US Patent Pending, submitted NSF Pronosein

"Developed new polyester-based hybrid material for sensor application containing crystals of inboluminescent Eu-complex (2 US patents pending, submitted Proposal for SBIR Program of NASA).

\*Co-authored 8 published articles, 9 patents and presented 7 papers at international and national conferences.

# University of Texas at Dallas, Department of Chemistry, Dallas, TX

1994-1997

Basic and applied research, development and analysis of new small molecules, such fluorescent monomers and model compounds, and light-emitting polymers:

\*Developed new vinylenearylene, terthiophene, benzimidazola and benzoxazole derivatives.

\*Created and investigated new poly(dialkoxyarylenevinylene)s for producing new materials for flat panel display technology.

"Developed new method of synthesis for aromatic polyamides and polyesters with chromophor fragments in the chain which have studied as materials for light-emitting diode applications.

\*Characterized new materials using HPLC, FT-IR, NMR, MS, UV-Vis, luminescence, GPC.

"Trained undergraduate and graduate students to use methods that have been developed.

"Co-authored 15 published articles and presented eight papers at international and national conferences."

# Texas Tech University, Department of Physics, Lubbock, TX Visiting Associate Professor

1993-1994

Research and development of new polymeric materials for use in scintillator devices:

"Created method of preparation for epoxypolymer-dye compositions to produce new ultrafest plastic scintillators and wavelength shifters.

\*Characterized new polymer-dye compositions by using time-resolved fluorescent technique.

\*Taught physics undergraduate courses,
\*Co-authored published 3 articles and presented paper at national meeting,

Fermi National Accelerator Laboratory, Batavia, IL

1993

Visiting Scientist

Research and development of new radiation stable polymeric materials for plastic scintillators:

\*Developed new copolymers of styrene with luminophore fragments in the chain and polystyrenedye compositions that proved to be effective new plastic scintillators,

"Created method of preparation for epoxypolymer scintillators with improved radiation stability. "Evaluated scintillation efficiency and spectral properties of new plastic scintillators.

\*Co-authored published article and presented paper at international conference.

Karpov Institute of Physical Chemistry, Moscow, Russia 1978-1994

#### Head of Chemistry Group

Basic and applied research, development and laboratory management in the area of small molecules, such as new reactive fluorescent dyee, and light-emitting polymers on their base, including investigation of proteins, containing fluorescent labels:

"Proposed new multistep synthetic routes for making fluorescent dyes with different reactive groups.

"investigated photophysical properties of proteins containing fluorescent sulfopyrene moieties.

\*inverted about eighty new colored and fluorescent polymers using copolymerization and copolygondensation techniques.

\*Commercialized new polymer-based materials (films, fibers, composites) with unique optical properties and high photo- and radiation stability.

\*Provided supervision of 6 Ph.D. and 4 M.S. students.

\*Authored 6 books, 75 published articles and 25 Russian invention's Certificates.

#### **PUBLICATIONS**

Six boxis (two of them "Fluorescent Polymers" and "Luminescence in Public Health" were published in English, four - in Russian), 95 published articles , 25 Russian Inventor's Certificates, two US patents and three European patents granted and 8 US patents cerding.

#### EDUCATION

2<sup>nd</sup> Phd (Degree of Doctor of Sciences in Polymer Chemistry and Physical Chemistry). Dissertation "Preparation of polymers with predicted spectral-turninescent properties by chemical modification of the molecular chein".

Karpov Institute of Physical Chemistry, Moscow,

Russia 1991

14 Ph.D. (Organic Chemistry and Polymer Chemistry), Dissertation "Synthesis and izomerization cyclication of aromatic polyovanoamides and polyovanourses"

Karpov Institute of Physical Chemistry, Moscow,

Ruseia 1978

.1975

2007-2009

M.S. (Chemical technology of organic synthesis). Institute of Fine Chemical Technology, Moscow Russia

PROFESSIONAL AFFILIATIONS AND RELATED ACTIVITIES

American Chemical Society
1995
Visiting Lecturer of Department of Chemistry at UNC at Charlotte
2003

Visiting Professor of Department of Chemistry at Eurasian National
University, Astana, Kazakhstan 2005-Present

The winner of 10 InnoCentive Challenges who has been nominated among 11 other most successful innoCentive Solvers with a Title "Top Solver of the Year 2007" and among 17 other most successful innoCentive Solvers with a Title "Top Solver

of the Year 2008" (see web site http://www.innocentive.com/serviets/project/Projectinfo.po?s=AW).

PERSONAL

US Citizen 2002

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thienna Ho

Serial No.: 10/599,779

Filed: 06/28/2007

Title: SKIN LIGHTENING METHOD

Art Unit: 1617

Examiner: Gina Yu

Declaration Under 37 CFR Section 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir or Madam:

I, the undersigned Sherilee J. Backman, declare and say:

1, I am a cosmetic chemist with over twenty years of technical experience in the cosmetics industry. My expertise includes formulating new products, including skincare, color, cosmetics, hair care, OTC drugs, and many other product types; assisting in and troubleshooting cosmetics manufacturing; providing technical documentation supported by experimental data; and communicating with customers as a liaison for various interest groups. I studied Biology as an undergraduate at Rensselaer Polytechnic Institute in Troy, NY; I later graduated from Rutgers College, Rutgers University, in NJ with a B.A. in Political Science. I have served as an Adjunct Professor for core courses in the Masters Program in Cosmetic Science at Fairleigh Dickinson University in Teaneck, NJ, and hold several patents in the area of novel raw material applications in cosmetic formulations. Further details concerning my academic

training, work experience, and activities are presented in my résumé attached as Exhibit A to the present declaration.

- I have reviewed the present patent application, Serial No. 10/599,779,
   Skin Lightening Method. I have also reviewed U.S. Patent No. 4,296,130 ("Herschler") and the office action of the present application dated November 13, 2009 discussing Herschler and other prior art references.
- 3. I reviewed the Herschler patent to determine whether it might disclose the concept of using methylsulfonylmethane (MSM) to lighten skin tone. Herschler discloses other uses of MSM for treating the skin, but does not in any way disclose or suggest that MSM is capable of lightening a subject's skin tone.
- 4. I reviewed the office action dated November 13, 2009 concerning the rejection of claim 1 for obviousness over Herschler, Webster's Ninth New Collegiate Dictionary's definition of "complexion," and International Patent Publication WO/1994/005479 ("Salim"). The examiner found Herschler's disclosure that MSM could be used to "beautify the complexion," together with a definition of "complexion" as "the color or appearance of skin," would have made it obvious to use MSM to lighten skin tone. This finding does not accurately reflect what would have been obvious to a cosmetic chemist when the present patent application was first filed as an international application in April 2005, as more fully explained below.
- 5. Herschler's use of the word "complexion" is limited only to the phrase "beautify the complexion." A cosmetic chemist of ordinary skill would not have understood "beautify the complexion" as used by Herschler to mean "lightening the skin tone." Instead, one of ordinary skill would have believed that to beautify the complexion meant to improve the skin's appearance by a cosmetic effect such as softening and smoothing. Herschler is limited to disclosing cosmetic effects of MSM, such as

softening and smoothing. In contrast, lightening the skin tone is more of a physiological effect, is not disclosed or discussed by Herschler at all, and is of a different nature than softening and smoothing.

- 6. It is self-evident from his disclosure that Herschler had not conceived of using MSM for skin lightening or brightening and therefore could not have used the phrase "beautify the complexion" to refer to any such effect. For example, Herschler does not mention vitiligo, hyperpigmentation, or any other disease affecting skin color, at all. His patent is focused on the stabilization of urea (carbamide) by combining it with MSM, and using this combination to "beautify the complexion" by softening and smoothing the skin. In column 3 of his patent, he writes "An object is to provide a stable, neutral vehicle for pharmaceuticals, which vehicle has no interfering or undesirable pharmacological activity." Furthermore, if Herschler were interested at all in skin lightening, he would have mentioned hydroquinone, or some other known skin lightening agent, in his table of "actives" in column 13. The fact that he mentions no such agent evidences his lack of knowledge or interest in skin lightening as an effect of his cosmetic compositions.
- 7. Even in isolation, that is, outside of the context of Herschler, to "beautify" the skin complexion would not have been understood as meaning or suggesting lightening of skin tone to a cosmetic chemist, because various cosmetics are known to both lighten and darken skin in pursuit of a more beautiful complexion. That is, to "beautify" does not imply either lightening or darkening of skin tone. Instead, to refer to making the overall skin tone lighter, a cosmetic chemist would have used the terms "lightening" or "brightening" the skin tone or complexion.

- 8. I have experience in the production and use of products for skin lightening and brightening, including products based on hydroquinone, ascorbic acid and its derivatives (including but not limited to various ascorbyl phosphates, ascorbyl glucoside, and other ascorbyl esters), kojic acid, and plant extracts including but not limited to those of arbutin, licorice and mulberry. These ingredients and combinations thereof. like MSM, are used to lighten skin tone. As a cosmetic chemist developing skin lighteners, I considered various alternatives and prospective substances to achieve skin lightening, without discovering any reference to MSM as a prospective skin lightener. In addition, the Herschler and Salim references contain nothing that would have led me to consider trying MSM as a prospective skin lightening agent. There is nothing in these references or otherwise reported in the prior art that I am aware of to suggest that MSM might have been expected to possess skin lightening properties. MSM's skin lightening effects as first reported by the inventor of the present application would therefore not have been considered expected or predictable at the time these effects were first reported by her in the present application.
- 9. Claim one of the present application is limited to "at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months." The references Herschier and Salim do not specifically disclose this dose regimen. Salim discloses an oral dose of MSM in units of 100 to 500 mg "at intervals of from 2 to 8 hours, most preferably every 6 hours" for therapeutic purposes such as healing injured skin, in combination with a sulfur-containing amino acid. Salim does not disclose a specific duration of treatment, a dose per unit of body weight, or a skin lightening effect. A cosmetic chemist of ordinary skill would understand Salim as disclosing a maximum dose of MSM in the range of 1500-2000 mg per day (500 mg three or four times daily, or smaller doses more frequently), in combination with one or more sulfur-containing amino acids in the same dosage range. For a relatively small 45 kg adult female, this equates to a maximum dose of MSM in the range of 33 to 44

mg/kg/day, which is much less than the at least 133 mg/kg/day specified in claim 1 of the present application,

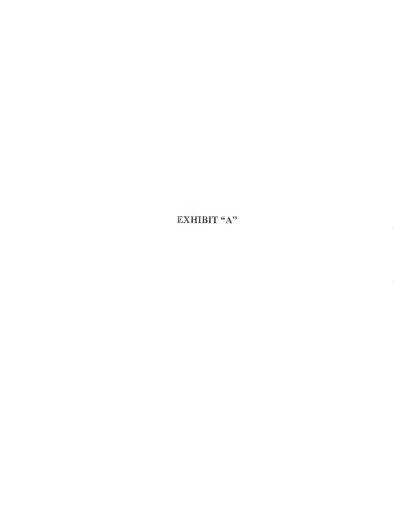
- 10. One of ordinary skill reading Herschler and Salim would not have been motivated to discover the higher dose range specified in claim 1, for several reasons. First, lower doses were already known to be effective for all known cosmetic and therapeutic applications, as demonstrated by the Herschler and Salim references. Second, there was no suggestion that higher doses of MSM would produce any beneficial effect, much less skin lightening. One of ordinary skill would therefore have had no apparent reason to experiment with higher doses.
- 11. In addition, the Salim reference is focused on the synergistic effect of sulfur-containing amino acids with MSM, predominately but not exclusively by topical administration. Most important, Salim demonstrated that increasing the concentration of MSM alone does not provide any additional benefit in reducing tissue injury. Specifically, in the tables reported on pages 11 and 13 of Salim, no additional benefit is shown for increasing concentration of MSM past 5% in ethanol administered orally. Therefore, Salim provides no incentive to experiment with higher doses, and if anything, might have discouraged such experimentation by reporting that increased concentrations of MSM provide no additional benefit.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful faise statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful faise statements may jeopardize the validity of the application of any patent issued thereon.

Respectfully submitted,

Date: *J. M. May 21, 2010* 

Sherilee J. Backman



# Sherilee J. Backman

64 Grove Street Brasileboro, VY 06391 T. 802-258-9005 C. 732-801-7542 personalicare/Bromail com

### Qualifications

Over twenty years of technical experience in the cosmetics industry. Strong skills in formulating very creative and innovative products, troubleshooting the manufacturing process, as well as in customer communication and oral and written presentations. Experienced in formulating skincare, color, cosmetics, haircare, OTC drugs, and many other products. Experienced in start-to-finish personal product development and commercialization. Adept at management, ingredient sales and distribution, and targeted markeling.

#### Experience

2008-Current Venus of Vermont, Inc. Braffleboro, VT

### **Technical Director**

Provide technical, sales and marketing expertise to select customers in the cosmetics and outraceuticals arenas.

2004-2007 DKSH North America, Inc. Baltimore, MD

Business Unit Manager, Personal Care & Food Ingredients

- Managed personal care and cosmetic, and food, beverage and nutraceutical ingredient product lines.
- Performed sales, marketing and technical services.
- Expanded client and product bases with multi-tiered marketing and sales strategies.
- Visited key customers, established subdistributors, agents and strategic alliances, and contracted materials suppliers.
- Covered territory of US. Canada and Central America.
- Coordinated services to multinational clients; established global pricing and resolved regulatory compliance issues.
- Sourced novel and unique raw materials for representation; found and evaluated principals and materials; helped develop and shared marketing and technical information; wrote contracts; participated on the DKSH PCI New Product Development team.
- Proposed establishment of a regional technical service division.
- Wrote and monitored divisional budgets totaling above \$3 million in sales.
- Established and coordinated logistics efforts; established warehousing and built costs into product price positions,
- Communicated with international colleagues daily.
- Developed advertising and company brand image awareness.
- Increased gross sales in cosmetics materials by nearly 60% within two years.
- Expanded cosmetic ingredient portfolio exponentially within two years.

1997-2004 SJH Consulting, Inc. Germantown, MO

#### President

- Provide cosmetic formulations, raw materials evaluations, and sourcing for goods and services.
- Guide product commercialization and production.
- Assist start-ups any way possible,

## Sherilee J. Backman n. 2

Fairleigh Dickinson University Hackensack, NJ 1998-2004

Adjunct Professor

 Teach Skin Care and Hair Care Formulation, and Raw Materials Evaluation, lecture courses for the School of Natural Sciences Mester's program in cosmetic sciences.

1998-2000 Cosmetech Laboratories, Inc. Fairfield, NJ

Vice President

Provided formulation and raw material evaluation guidence to customers and stall.

Promoted customer relations with innovative technology

Piscalaway, NJ

Hawthome, NY

1995-1997 Presperse Inc. **Technical Manager** 

Managed full-service supplier laboratory and staff.

Oversew QC, applications, technical service and sampling functions.

Designed and oversaw experimental raw material evaluations.

Established standard operational procedures in the laboratory.

1993-1996 Rone®/FM Industries

Senior Applications Chemist

Provided prototype formulations and oversaw substantiation testing.

Devised technical programs for new and existing raw materials.

Helped establish materials specifications.

Provided technical service to customers.

Wrote and assessed supplier literature.

## Affiliations and Honors

SCC; CTFA Sunscreen Task Force and Steering Committee. RPI Honors List. Rulgers Deans List; member, Alpha Sigma Lambda Honors Fratemity; NYSCC Chapter Historian. gelent bolder.

#### Skills

- Successfully pitch product approaches and materials to customers.
- Creats innovative and patent-able product formulations
- Provide assistance in start-to-finish product commercialization.
- Formulate, both from scratch and from prototype, a wide variety of cosmello systems throughout the range of skincare, halroare, color cosmetic and treatment products (q.v. attached listing).
- Color-matching.
- Trouble-shoot production/manufacturing process.
- Provide customer technical support, including developing presentations
- Versatile in computer software applications.
- Able to perform accurate benchwork guickly and efficiently.
- Coordinate multiple groups of people and projects.

# Sherilee J. Backman p. 3

Products developed include:

Skin Care

daily use moisturizing creams and lotions for body, hands, face, feet, undereye, etc.

moisturizing gels and serums

water-in-oil and water-in-silicone benier creams and loticos

body mousses

alpha- and beta-hydroxy products

mixed emulsions

licraid crystal emulsions

low-energy emulsions

spray emulsions

baby products

deansing milks, creams, toners

NPA-approved and certified organic products

Hair Care shampoos

2-In-1 and 3-in-1 shampoos

conditioners

hair repair and alessing products hair gels

hair sprays (natural pump and aerosol) hair mousses

cerms

depilatories

temporary and semi-permanent hair dyes

hair mascaras anti-dandruff preparations

dry shampoos

heat-activated preparations

Color Cosmetics

amulsion foundations (oil-in-water, water-in-oil, water-in-eilicone, mixed)

anhydrous foundations and concealers

transfer-resistant foundations and concealers fine-line-minimizing foundations and powders

pressed powder wet/dry foundations

eyeshadows (pressed and anhydrous)

moisturizing lipsticks

extended wear lipsticks

transfer-resistant lipsticks

inglosses

conditioning mascaras

waterproof mascaras

lash-extending, building, and curling mascaras

brow mascaras

liquid eveliners

blushers (pressed powder and anhydrous)

Sherilee J. Backman p. 4

loose powders

edible body paint children's nail ename!

#### Ethnic Products

skin lightening creams, lotions, gels and serums

facial and undereve lighteners skin clarifiers and brighteners dry skin emulsions

hair relaxers

facial depilatories

hair styling pomades, gels, creams, sprays hair glossing and managing preparations

make-up foundations pressed-powder blushes

insticks

### Spa Products

hath salls bath oils

bath and shower cleansers scrub emulsions, gels, salts

massage oils, gels, bars arometherapy emulsions, balms, oils, salts clay and mud emulsions and masques preparations with incorporated encapsulates, herbs

#### Treatment. Hygiene, and OTC Drug Products

organic and inorganic sunscreen emulsions, sticks, gets, sprays, oils and solutions from SPF 2-50+

children's sunscreen products

water- and sweat-resistant sunscreen products

self-tanner emulsions, gels, sprays

insect repellent emulsions, oils, sprays nail and cuticle treatment creams, gels, balms

depilatories skin lighteners

toothoastes

mouthwashes vaginal lubricants

skin protectant creams, lotions, mousses anti-acnes lotions, creams, make-up foundations, blotters and concealers

medicated washes cleansing wipes

anti-cellulite emulsions and gels

in balms

oil-control preparations

stick, roll-on, gel, and clear antiperspirants

# Sherilee J. Backman n.s

decdorants

topical analgesic emulsions, gels, sticks tooth bleaching systems

Fragrances and Ancillaries

perfilmes, colognes, edp's, edf's, aftershaves moisturizing fragrances clear fragrance sticks fragrance balms and pornades bubble colognes ine-extension creams, lotions, gels, cleaneers

Page 37

# APPENDIX C

# RELATED APPEALS AND INTERFERENCES

NONE.